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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/616,371 03/15/96 STAMLER

J DUK96-03

EXAMINER

18N2/0319

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ART UNIT

PAPER NUMBER

1811

DATE MAILED:

03/19/97

**Please find below and/or attached an Office communication concerning this application or proceeding.**

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This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

DATE MAILED:

- ☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_ ☐ This action is made final.  
*for restriction purposes only.*

A shortened statutory period for response to this action is set to expire 1-month from the date of this letter.  
Failure to respond within the time period will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENTS ARE PART OF THIS ACTION:**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                   |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449              | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____  |

**Part II SUMMARY OF ACTION**

1. ☒ Claims 1-27 are pending in the application.  
Of the above claims, \_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_ are allowed.
4. ☐ Claims \_\_\_\_ are rejected.
5. ☐ Claims \_\_\_\_ are objected to.
6. ☒ Claims 1-27 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on \_\_\_\_ has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under 35 USC 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_; filed on \_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

**EXAMINER'S ACTION**

08/616,371

Art Unit: 1811

## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 6-8, drawn to methods of using a nitrosating agent for methods affecting NO or O<sub>2</sub> metabolism, classified in class 514, subclasses 19, 550 etc depending upon the nitrosating agent..

✓ II. Claims 4 and 22, drawn to a method for preserving organs using S-nitrosated hemoglobin, classified in class 435, subclass 1.1+.

III.. Claim 5, drawn to a method for treating malaria by use of nitosothiol and blood replacement therapy, classified in class 524, subclass 532+ and Class 604, subclass 4+.

IV. Claims 9-21 and 23-27, drawn to an SNO-Hb[FeII]O<sub>2</sub> preparation, a method of making and use in therapy, classified in class 514, subclass 6+.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions IV and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

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The methods of claims 23-27 address the treatment of different diseases involving different hosts and method steps and represent patentably distinct methods as compared to the use of S-nitrosated hemoglobin to preserve organs, which represents a non-therapeutic method.

3. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function and different and additionally utilize different compounds in different methods which achieve totally different objectives .

4. Inventions I and III compared to II and IV, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions utilize different compounds in different methods which achieve totally different objectives .

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification; the search required for the different Groups is different; and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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6. Claims 1-3 and 6-8 are generic to a plurality of disclosed patentably distinct species comprising different nitrosating agents including (but not limited to): organic nitrates, S-nitroso-N-acetyl cysteine (e.g. see specification page 8). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

**General information regarding further correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (703) 308-0254.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 17, 1997

Bennett Celsa

  
**CECILIA J. TSANG**  
**SUPERVISORY PATENT EXAMINER**  
**GROUP 1800**